ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Continuous quality assurance program" or "CQA program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.

"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-620. ~~Reserved~~ Continuous Quality Assurance Program

A. Each pharmacy permittee shall implement or participate in a continuous quality assurance (CQA) program. A pharmacy permittee meets the requirements of this Section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:

1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

B. A pharmacy permittee or the pharmacist-in-charge shall ensure that:

1. The pharmacy develops, implements, and utilizes a CQA program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The medication error data generated by the CQA program is utilized and reviewed on a regular basis, as required by subsection (D); and
3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

C. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the operation and management of the pharmacy's CQA program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The policies and procedures shall address a planned process to:

1. Train all pharmacy personnel in relevant phases of the CQA program;
2. Identify and document medication errors;
3. Record, measure, and analyze data collected to:
   a. Assess the causes and any contributing factors relating to medication errors, and
   b. Improve the quality of patient care;

4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and
5. Communicate periodically, and at least annually, with pharmacy personnel to review CQA program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQA program findings.

E. The Board's regulatory oversight activities regarding a pharmacy's CQA program are limited to inspection of the pharmacy's CQA policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

F. A pharmacy's compliance with this Section shall be considered by the Board as a mitigating factor in the investigation and evaluation of a medication error.